

Practitioner's Docket No. 576.02-US

CHAPTER II

TRANSMITTAL LETTER  
TO THE UNITED STATES ELECTED OFFICE (EO/US)  
(ENTRY INTO U.S. NATIONAL PHASE UNDER CHAPTER II)

PCT/US99/11693	26 May 1999 (26.05.99)	28 May 1998 (28.05.98)
International Application Number	International Filing Date	International Earliest Priority Date

TITLE OF INVENTION: OPTICAL METHOD AND APPARATUS FOR DETERMINING FERTILITY STATUS

APPLICANT(S): Duo Management International, LLC; MOON, Margaret E.; VAUGHAN, Sheila C. and RAFFENSPERGER, Susan M.

Box PCT  
Assistant Commissioner for Patents  
Washington D.C. 20231  
ATTENTION: EO/US

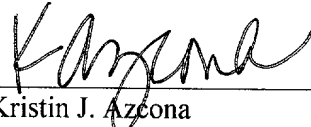
- Applicant herewith submits to the United States Elected Office (EO/US) the following items under 35 U.S.C. section 371:

CERTIFICATION UNDER 37 C.F.R. section 1.10\*

(Express Mail label number is **mandatory**.)

(Express Mail certification is optional.)

I hereby certify that this paper, along with any document referred to, is being deposited with the United States Postal Service on this date **November 28, 2000**, in an envelope as "Express Mail Post Office to Addressee," mailing Label Number EL605629275US, addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

  
Kristin J. Azcona

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- a. This express request to immediately begin national examination procedures (35 U.S.C. section 371(f)).

2. Fees

CLAIMS FEE*	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATIONS
BASIC FEE	TOTAL CLAIMS	14 - 20 =	0	x \$18.00 =	\$0.00
	INDEPENDENT CLAIMS	1 - 3 =	0	x \$78.00 =	\$0.00
	MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$260				\$0.00
	Claims meet PCT Article 33 (1)-(4) - IPEA - US				\$100.00
	Total of above Calculations				= \$100.00
SMALL ENTITY	Reduction by 1/2 for filing by small entity, if applicable. Affidavit must be filed (note 37 CFR 1.9, 1.27, 1.28).				- \$50.00
	Subtotal				\$50.00
	Total National Fee				\$0.00
	Fee for recording the enclosed assignment document \$40.00 (37 CFR 1.21(h)). (See Item below). See attached "ASSIGNMENT COVER SHEET".				\$0.00
TOTAL	Total Fees enclosed				\$50.00

3. A copy of the International application as filed (35 U.S.C. section 371(c)(2)) is not required, as the application was filed with the United States Receiving Office.
4. A translation of the International application into the English language (35 U.S.C. section 371(c)(2)) is not required as the application was filed in English.
5. Amendments to the claims of the International application under PCT Article 19 (35 U.S.C. section 371(c)(3)) are transmitted herewith.
6. A translation of the amendments to the claims under PCT Article 19 (38 U.S.C. section 371(c)(3)) is not required as the amendments were made in the English language.
7. A copy of the international examination report (PCT/IPEA/409) is not required as the application was filed with the United States Receiving Office.
8. Annex(es) to the international preliminary examination report is/are not required as the application was filed with the United States Receiving Office.

**OPTICAL METHOD AND APPARATUS FOR DETERMINING FERTILITY STATUS**

This application claims the benefit of U.S. provisional application number 60/086,987 incorporated herein by reference in its entirety.

**5    Field of The Invention**

The field of the invention is biomedical diagnostics.

**Background of The Invention**

Conception typically occurs during the period of the menstrual cycle called "ovulation" in humans, which is expected to last about six days. Monitoring ovulation is of great significance, because knowing the time of ovulation enables women to manage their reproductive period. When pregnancy is desired, monitoring of ovulation can be used to find the relatively narrow window of fertility within a menstrual cycle. When pregnancy is not desired, monitoring ovulation can be used as an alternative to classical methods of contraception by determining times of sexual abstinence or use of contraceptives.

15    Many ways of monitoring ovulation are known in the art, and may be broadly characterized as falling within one of two categories. The first category of monitoring ovulation comprises clinical diagnostic methods that are typically available only in hospitals or in a physicians office. Clinical diagnostic methods include sonography, and ELISA based methods to quantify various reproductive hormones. Such methods are relatively accurate, however, clinical  
20    diagnostic methods typically involve a significant cost and inconvenience to the patient.

25    The second category of monitoring ovulation comprises "home" diagnostic methods. Home diagnostic methods can typically be performed with a minimal amount of equipment, and generally rely on simple physical or biochemical observations. Physical observations include, for example, the monitoring of the woman's body temperature. Body temperature testing is based upon the fact that a woman's normal body temperature rises slightly during ovulation. However, improper technique of determining the body temperature may lead to significant inaccuracy. Furthermore, minor infections, stress, and dietary influences may cause fluctuations in the body temperature and make this method relatively inaccurate. Biochemical observations include quantitative tests of reproductive hormones in urine. For example, home tests to determine the

level of luteinizing hormone or progesterone in urine are commercially available over the counter. Home based urine tests are typically easy to perform, and require little time. However, home based urine tests tend to be expensive, especially when repeated over a longer period of time.

5           The time of ovulation can also be determined by observing the appearance of crystallized saliva (i.e. saliva that has been allowed to dry at room temperature). It is known in the art that hormonal changes during a woman's menstrual cycle affect the appearance of crystallized saliva, manifested as formation of characteristic crystals that can be observed using a magnification device (see Figure 1).

10           Determination of ovulation by microscopic observation of crystallized saliva is advantageous because it is inexpensive, relatively accurate and follows a simple protocol that allows even the inexperienced user to obtain reliable test results. Moreover, microscopic observation of crystallized saliva is accurate even when menstrual cycles are erratic, ovulation is irregular, or menstrual disturbances are experienced. Furthermore, microscopic observation of  
15           crystallized saliva is a non-invasive and painless method that can be performed discretely and relatively quickly.

          Various optical systems are known in the art to help determine ovulation by microscopic observation of crystallized saliva. U.S. Pat. No. 4,737,016 to Russell et al., for example, describes a portable handheld microscope with a single lens. Although the portable handheld  
20           microscope can be used to observe a crystallized saliva sample, it is originally designed to view small insects or other small objects, and sample handling is therefore rather cumbersome.

          In another example, U.S. Pat. No. 5,062,697 to Mitchell, a handheld microscope is presented wherein a test sample can be compared with a reference sample in a single step. However, manual focussing is required, complicating the use of the device. Furthermore,  
25           batteries and an intact light bulb are needed to provide transillumination of the sample.

          In a further example, U.S. Pat. No. 5,639,424 to Rausnitz, up to 30 samples can be viewed on a sample disc in a portable fertility tester. The sample disc, however, introduces an additional part that is essential to the function of the tester. If the disc is broken or lost, no more

tests can be performed. Moreover, the advantage of accommodating up to 30 samples disadvantageously leads to a larger test device.

In still further examples, U.S. Pat. No. 5,572,370 to Cho, and U.S. Pat. No. 4,815,835 to Ortueta Corona, fertility testers are described, in which the optical device has to be disassembled in order to apply a sample of saliva. Disassembling, applying the sample, reassembling and adjusting the focus of the fertility tester, and holding down the light switch, however, requires at least some degree of dexterity, which might be problematic for some users.

Viewing a magnified crystallized saliva sample using lenses typically requires a relatively strong light source. Most known fertility testers use batteries and a light bulb or an LED as a light source, which tends to be problematic in some countries, especially in third world countries. Moreover, the use of batteries demands appropriate battery recycling when a negative impact to the environment is to be avoided.

The fertility tester "PFT 1-2-3" avoids problems with built-in backlighting devices by using ambient light. In the "PFT 1-2-3", various color filters are mounted on one disc and a miniature lens is mounted on a second disc. Both discs are rotatably connected at their center, and lens and color filter have to be aligned by turning the miniature lens-containing disc relative to the filter-containing disc to examine a crystallized saliva sample. Although the two discs are spaced in such a way that the crystallized saliva sample is in focus, the miniature lens does not allow substantial tolerance in the distance between the two discs. Therefore, manual pressure has often to be applied to both discs in order to refocus. Moreover, due to the small size of the magnifying lens, the observation area is relatively small.

In most or all devices known in the art to visually inspect a crystallized saliva sample, an optical system must be focused. To obtain a sharp image of the crystallized saliva, the distance between the crystallized saliva and an eyepiece is usually altered. However, focussing an optical system usually requires some practice and may be cumbersome, especially for the inexperienced user. Moreover, focusing optical systems typically requires moving parts that may be subject to malfunction, possibly leading to false-positive or false-negative test results.

In general, many devices to determine ovulation by observing crystallized saliva are known. However, such devices typically suffer from one or more difficulties including problematic sample application, need of an internal light source, or problematic focussing of the eyepiece on the sample. Therefore, there is a need to provide apparatus and methods to solve these problems.

### **Summary of the Invention**

Methods and apparatus for determining a woman's fertility status are provided in which a sample is consistently viewed in focus through an optical system, without altering the distance between the eyepiece and the sample receiving surface.

In preferred embodiments the optical system includes at least two lenses, and optionally includes a filter. It is also preferred that the bodily fluid is saliva or vaginal fluid.

Various objects, features, aspects and advantages of the present invention will become more apparent from the following detailed description of preferred embodiments of the invention, along with the accompanying drawings in which like numerals represent like components.

### **Brief Description of The Drawings**

Figure 1 is a collection of prior art photomicrographs of samples of crystallized saliva.

Figure 2 shows a schematic of a fertility tester embodying the inventive subject matter.

Figure 3 shows a top view of the fertility tester of Figure 2.

Figure 4 shows general outlines of alternative shapes of the fertility tester of Figure 2.

### **Detailed Description**

In Figure 2, a fertility tester 10 has generally an optical system 20, a top cover 30, a bottom cover 40, and a case 50. The optical system 20 has an optical chamber 21, a condenser 22, a first lens 24, a second lens 26, a protective window 28, and a sample receiving surface 29.

With respect to the material of preferred fertility tester 10, all parts can be fabricated from injection-molded acrylic. However, many other materials may also be used, including natural and synthetic polymers, metals and glass and any reasonable combination thereof. For example, appropriate alternative materials are polycarbonate, polyethylene, wood, aluminum, and optical glass.

Fertility tester 10 is shown in Figures 2 and 3 as a round disk. Various other shapes, however, are also contemplated, including rectangular and polygonal shapes. Some examples of alternative shapes are shown in Figure 4 and many more alternative shapes can be made without departing from the inventive concepts presented herein.

Fertility tester is preferably approximately 5" in diameter and about 1.5" thick. However, many other dimensions are also contemplated as long as they accommodate optical system 20.

Cover 30 and cover 40 are preferably coupled to case 50 using acrylic hinges 32 and 42. However, many other covers and methods of affixing covers to case 50 are contemplated, that cover the protective window and the sample receiving surface. For example, alternative covers could be pivotably, slidably or rotatably coupled to case 50, and may or may not be permanently attached to case 50.

It is contemplated that case 50 may comprise additional elements, including a pocket, a mirror, a chart to enter fertility status, reference pictures of crystallized saliva, instructions for use, etc. It is further contemplated that case 50 need not necessarily have a top cover or a bottom cover. Alternative fertility testers may therefore have only optical system 20, case 50 and bottom cover 40.

Optical system 20 further comprises optical chamber 21, protective window 28, first lens 24, second lens 26, condenser 22, and sample receiving surface 29.

Optical chamber 21 is preferably statically mounted in case 50. In alternative embodiments, however, many other ways of mounting the optical chamber to a case are contemplated, including mountings wherein the optical chamber is slideably, pivotably or rotatably coupled to a casing.

Optical chamber 21 is preferably made from non-transparent, tinted, injection-molded acrylic. Optical chamber 21 contains a multi-lens system of two bi-convex acrylic lenses 24, 26, each of which are molded to two annular acrylic spacer elements. Optical chamber 21 further comprises an acrylic protective window 28 opposite to the sample receiving surface 29. In alternative embodiments, various other materials may be used for optical chamber, lenses, annular spacers, and protective window, including transparent synthetic polymers, glass, and metals. For example, alternative lenses may be made from optical glass or polystyrene, annular spacers may be made from polypropylene, optical chambers may be made from steel or brass, and an alternative protective window may be made from transparent polyvinyl chloride.

In Figure 2, the bi-convex lenses 24, 26 are prefocused to the sample receiving surface 29, and have a combined magnification of preferably 40x-100x, and more preferably 50x-60x. However, many other arrangements of optical elements are also contemplated, including single lenses, multiple lenses of various characters (e.g. bi-convex, bi-concave, convex-concave, etc.), condenser elements, and filters. For example, contemplated lens systems include systems having two bi-convex and one plano-concave lens. A single lens with an 85x magnification is also contemplated. Contemplated condenser elements may be reflective, refractive, or diffractive. The condenser element may be used to enhance illumination of the sample, for example, using dark-field illumination to increase the contrast of the sample. Appropriate filters include polarizing filters, spectral cut-off filters, or filter groups.

In a preferred embodiment, sample receiving surface 29 is a transparent, approximately 1mm thin, rounded off square surface, which is an integral part of optical chamber 21. In alternative embodiments, sample receiving surface 29 may be separable from optical chamber 21. For example, an alternative sample receiving surface includes a glass or transparent polymer surface that may or may not be tinted.

Regardless of the arrangement and number of optical elements in optical system 20, the optical elements are situated such that the optical system is prefocused with regard to sample receiving surface 29.

The term "depositing the sample" as used herein means that the sample is transferred directly or indirectly from the source to the sample receiving surface. A direct transfer, for



example, is licking the surface of the sample receiving surface. An indirect transfer, for example, is applying vaginal fluid from a vaginal swab to the sample receiving surface.

As used herein, the term "bodily fluid" refers to saliva and vaginal fluid and the bodily fluid may be manually collected or with the help of a sampler. Typically, a few microliters of  
5 bodily fluid are sufficient for determining the fertility status.

As used herein, the term "ovulation" and "fertile period" are used interchangeably, and both reflect the time during a menstrual cycle during which conception is possible.

As used herein, the term "eyepiece" refers to the lens closest to the eye.

In a preferred method of determining a woman's fertility status, a woman transfers a drop  
10 of saliva from her mouth onto a fingertip. The saliva on the fingertip is then wiped over the sample receiving surface. In alternative embodiments, the bodily fluid need not be saliva, but may be various other bodily fluids, including vaginal fluid. Moreover, the bodily fluid need not be transferred onto a fingertip, but may also be transferred in other ways, including direct and indirect application. For example, direct application includes dripping of saliva from the mouth  
15 onto the sample receiving surface. An example of indirect application is swabbing the surface of a woman's inner cheek with an applicator, and then wiping the applicator over the sample receiving surface.

The saliva on the sample receiving surface is then dried, preferably at room temperature  
20 for about 10min. However, many other ways of drying are also contemplated, including drying at temperatures above or below room temperature. For example, drying may be performed at temperatures of about 30°C to 60°C, or even higher. In another example, drying may be done at temperatures between about 4°C-20°C. Furthermore, the time of drying need not be restricted to 10min, but may vary considerably between a few seconds and several hours, depending on the temperature and amount of bodily fluid. Appropriate drying times are, for example, 10 to 30  
25 seconds, but also 30 minutes, and longer.

After drying the bodily fluid on the sample receiving surface, the bodily fluid is inspected using the optical system, and the appearance of the bodily fluid is correlated with a reference. During inspection, the fertility tester is preferably held such that ambient light passes through the

bodily fluid and eyepiece into the eye of the observer. The protective window is preferably at a distance of about ½" to 1" from the eye of the observer, and the sample receiving surface points toward an ambient light source.

In a preferred embodiment, the ambient light source is preferably an incandescent light bulb. However, in alternative embodiments the ambient light source may be various other light sources including sunlight, fluorescent light bulbs, etc. Furthermore, it is not essential that the protective window is at a distance of ½" to 1" from the eye of the observer, but many other distances are also contemplated.

The reference is preferably a reference chart as depicted in Figure 1 that shows three magnified images of dried saliva, corresponding to a period that is regarded as fertile, possibly fertile, and infertile. In alternative embodiments, however, many other references may be used, including memorized images of dried bodily fluids, and sample images that can be viewed together with dried bodily fluid. In further alternative embodiments, the number of reference images need not be limited to three, but may vary between one and 28, or even more. In still further alternative embodiments, the reference may include additional elements, including a report chart in which test results can be noted.

Thus, specific embodiments and applications of determining a woman's fertility status have been disclosed. It should be apparent, however, to those skilled in the art that many more modifications besides those already described are possible without departing from the inventive concepts herein. The inventive subject matter, therefore, is not to be restricted except in the spirit of the appended claims.

**AMENDED CLAIMS**

[received by the International Bureau on 2 November 1999 (02.11.99);  
original claim 1 amended; remaining claims unchanged (1 page)]

1. A method of determining a woman's fertility status comprising:  
  
providing an optical system having a non-removable sample receiving surface and an eyepiece, such that a sample is applied to the sample receiving surface and consistently viewed in focus through the optical system without altering a distance measured between the eyepiece and the sample receiving surface;  
  
providing a sample of a bodily fluid from a female;  
  
depositing the sample at the sample receiving portion;  
  
drying the deposited sample and inspecting the dried sample using the optical system; and  
  
correlating the appearance of the dried sample with a reference.
2. The method of claim 1, wherein the optical system comprises a multi-lens system.
3. The method of claim 2, wherein the geometry of at least one lens is a mirror image of another lens.
4. The method of claim 1, wherein the optical system further comprises a condenser.
5. The method of claim 4, wherein the condenser reflects light through the dried sample.
6. The method of claim 4, wherein the condenser is a refractive condenser.
7. The method of claim 1, wherein the optical system further comprises a filter.
8. The method of claim 1, further comprising providing a protective cover over the optical system.
9. The method of claim 8, wherein the protective cover comprises at least one of a top cover and a bottom cover.

10. The method of claim 9, wherein the at least one of a top cover and a bottom cover is slideably coupled to the optical system.
11. The method of claim 9, wherein the at least one of a top cover and a bottom cover are pivotably coupled to the optical system.
- 5 12. The method of claim 1, wherein the bodily fluid of a female is selected from the group consisting of saliva and vaginal fluid.
13. The method of claim 1, wherein the step of drying the sample comprises air drying at room temperature for 10min.
- 10 14. The method of claim 1, wherein the reference is a reference chart comprising at least one reference image from a fertile period, one reference image from a transition period, and one reference image from a infertile period.

**ABSTRACT**

An optical method of determining a woman's fertility status is provided, wherein an optical system has a sample receiving surface and an eyepiece, such that the sample can be viewed in focus through the optical system without altering the distance between the eyepiece and the sample receiving surface using ambient-light illumination. A sample of a bodily fluid from a female is deposited at the sample receiving surface of the optical system and dried. The dried sample is then inspected using the optical system and the appearance of the dried sample is correlated with a reference.

# MAGNIFIED PICTURE OF SALIVA

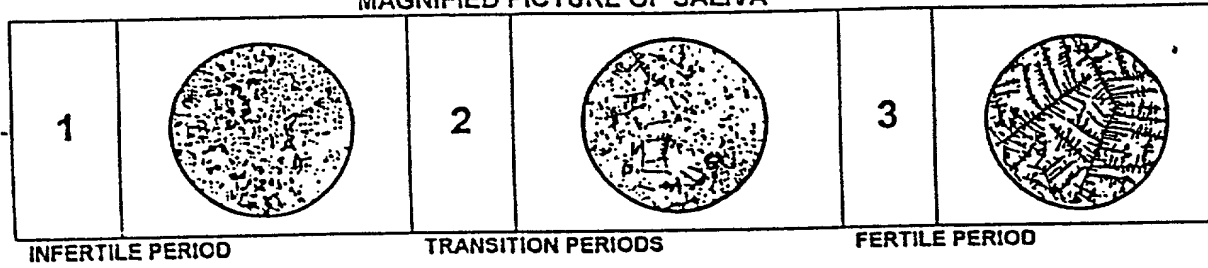


Figure 1

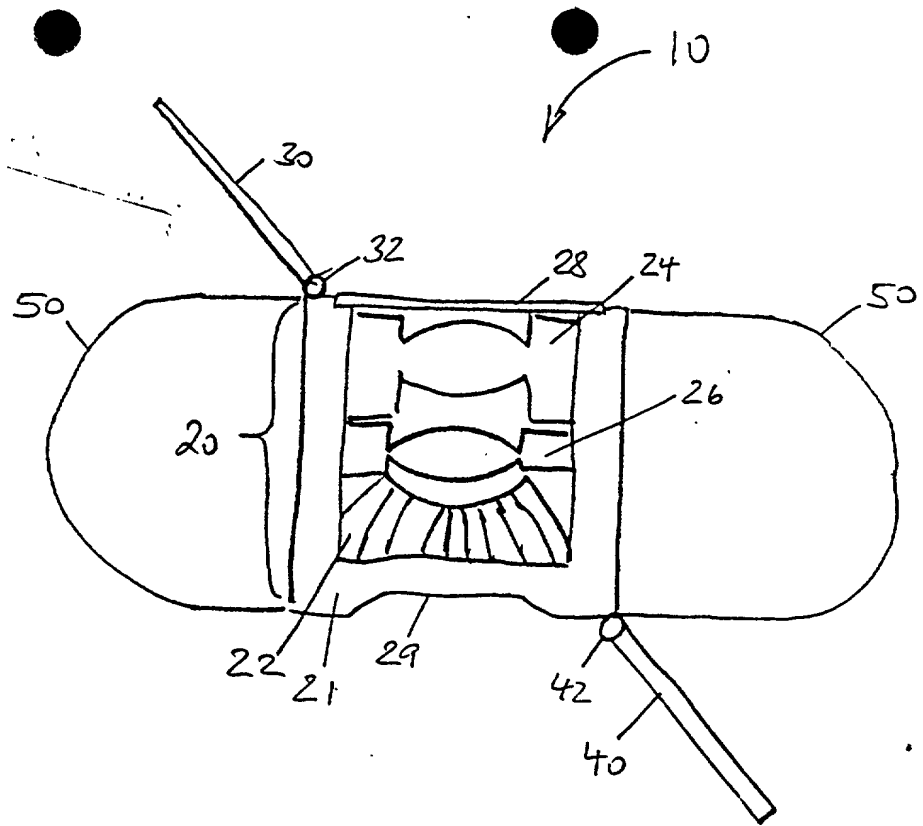


Figure 2

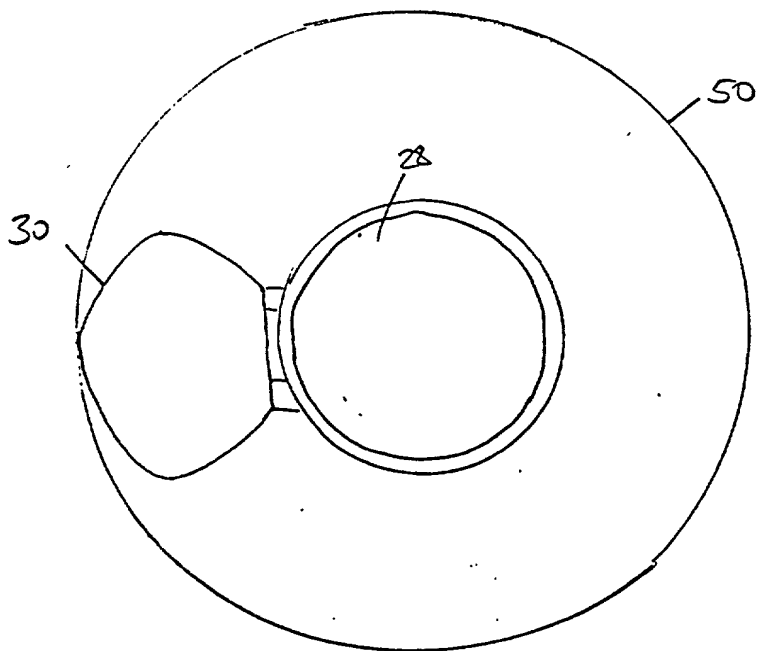
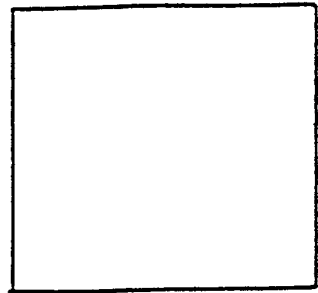
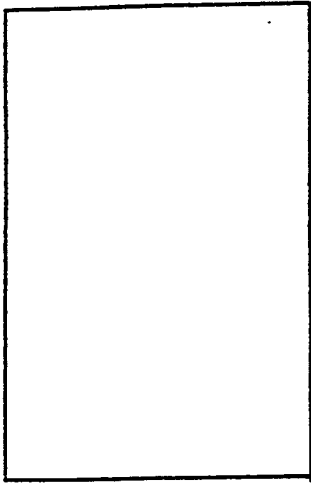


Figure 3

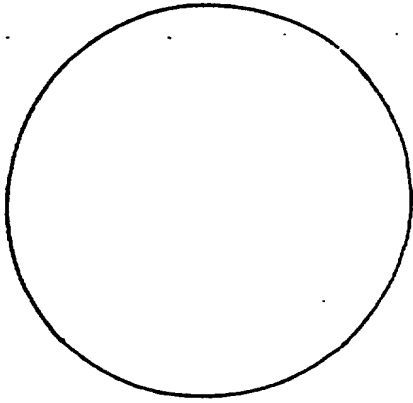




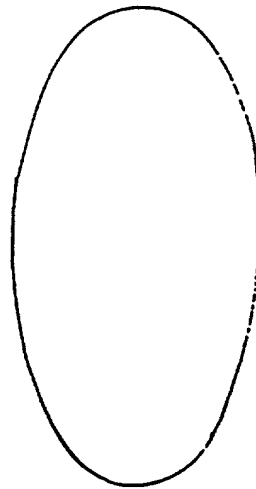
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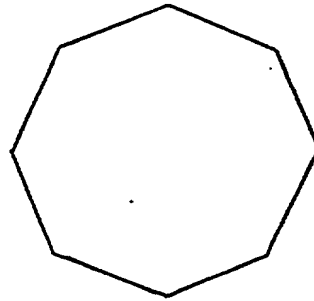
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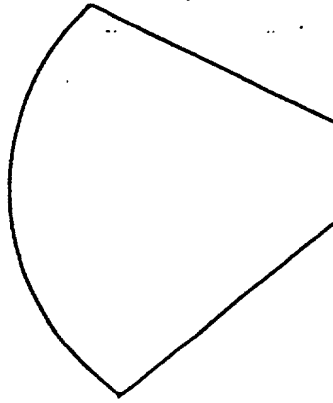
**C - ROUND**



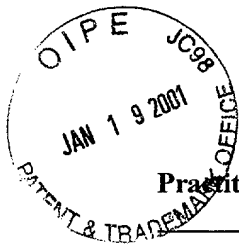
**D - OVAL**



**E - OCTAGON**



**F - SHELL/FAN**



Practitioner's Docket No. 576.02-US

PATENT

## COMBINED DECLARATION AND POWER OF ATTORNEY

(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL,  
CONTINUATION, OR C-I-P)

As a below named inventor, I hereby declare that:

### TYPE OF DECLARATION

This declaration is for a national stage of PCT application.

### INVENTORSHIP IDENTIFICATION

My residence, post office address and citizenship are as stated below, next to my name. I believe that I am an original, first and joint inventor of the subject matter that is claimed, and for which a patent is sought on the invention entitled:

### TITLE OF INVENTION

OPTICAL METHOD AND APPARATUS FOR DETERMINING FERTILITY STATUS

### SPECIFICATION IDENTIFICATION

The specification was described and claimed in PCT International Application No. PCT/US99/11693 filed on May 26, 1999.

### ACKNOWLEDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information, which is material to patentability as defined in 37, Code of Federal Regulations, Section 1.56, and which is material to the examination of this application, namely, information where there is a substantial likelihood that a reasonable Examiner would consider it important in deciding whether to allow the application to issue as a patent.

### PRIORITY CLAIM (35 U.S.C. Section 119(a)-(d))

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international

application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

Such applications have been filed as follows.

**PRIOR PCT APPLICATION(S) FILED WITHIN 12 MONTHS  
(6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION  
AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. SECTION 119(a)-(d)**

INDICATE IF PCT	APPLICATION NUMBER	DATE OF FILING DAY, MONTH, YEAR	PRIORITY CLAIMED UNDER 35 USC 119
PCT	PCT/US99/11693	26 May 1999	YES

**CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S)  
(35 U.S.C. Section 119(e))**

I hereby claim the benefit under Title 35, United States Code, Section 119(e) of any United States provisional application(s) listed below:

**PROVISIONAL APPLICATION NUMBER**

**FILING DATE**

60/086,987

May 28, 1998

**POWER OF ATTORNEY**

I hereby appoint the following practitioner(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

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**REGISTRATION NUMBER(S)**

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Bruce FERTEL

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Customer Number 24392

### DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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3-00 Susan M. RAFFENSPERGER

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